

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 25

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte C. ALEXANDER TURNER JR.,
BRIAN MATHUR, and D. WADE WALKE

Appeal No. 2004-1843
Application No. 09/878,764

ON BRIEF

Before WILLIAM F. SMITH, MILLS, and GRIMES, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1-4, all of the claims remaining [check this]. Claim 1 is representative and reads as follows:

1. An isolated nucleic acid molecule comprising a nucleotide sequence encoding an amino acid sequence drawn from the group consisting of SEQ ID NO:2 and SEQ ID NO:4.

The examiner relies on the following references:

Robson et al. (Robson), "Introduction to Proteins and Protein Engineering," Elsevier, p. 41 (1986)

Bork et al. (Bork), "Sequence and topology Deriving biological knowledge from genomic sequences," Current Opinion in Structural Biology, Vol. 8, pp. 331-332 (1998)

Ji et al. (Ji), "G Protein-coupled Receptors," The Journal of Biological Chemistry, Vol. 273, No. 28, pp. 17299-17302 (1998)

Skolnick et al. (Skolnick), "From genes to protein structure and function: novel applications of computational approaches in the genomic era," Tibtech, Vol. 18, pp.34-39 (2000)

Yan et al. (Yan), "Two-Amino Acid Molecular Switch in an Epithelial Morphogen That Regulates Binding to Two Distinct Receptors," Science, Vol. 290, pp. 523-527 (2000)

Claims 1-4 stand rejected under 35 U.S.C. §§ 101 and 112, first paragraph, as lacking patentable utility.

We affirm.

Technical Background

The specification discloses polynucleotides encoding human proteins (referred to as "novel G protein coupled receptors" or NGPCRs) that "have structural motifs found in the 7TM receptor family. . . . The described NGPCRs have multiple transmembrane regions (of about 20-30 amino acids) characteristic of 7TM proteins as well as several predicted cytoplasmic domains." Page 2. The specification discloses that the encoded proteins "are transmembrane proteins that span the cellular membrane and are involved in signal transduction after ligand binding." Id. See also pages 4-5: "In addition to 7TM proteins, the presently described NGPCRs share significant homology with a domain of latrophilin (latrotoxin receptor) and peptide hormone receptors."

The specification does not disclose any ligands that bind to the proteins of SEQ ID NO:2 and SEQ ID NO:4, nor what signal is transduced by the proteins in response to ligand binding, nor what role either protein plays in any physiological process. Nonetheless, the specification contemplates “methods of using the described NGPCR gene and/or NGPCR gene products for the identification of compounds that modulate, i.e., act as agonists or antagonists, of NGPCR gene expression and or NGPCR gene product activity. Such compounds can be used as therapeutic agents for the treatment of various symptomatic representations of biological disorders or imbalances.” Page 4.

The specification also discloses that “an additional aspect of the present invention includes knockout cells and animals having genetically engineered mutations in the gene encoding the presently described NGPCRs.” Page 2. However, the specification does not disclose that any such knockout cells or animals were made, nor what phenotype(s) they would have been expected to show.

The specification discloses that “[t]he NGPCR proteins or peptides, NGPCR fusion proteins, NGPCR nucleotide sequences, host cell expression systems, antibodies, antagonists, agonists and genetically engineered cells and animals can be used for screening for drugs . . . effective in the treatment of the symptomatic or phenotypic manifestations of perturbing the normal function of NGPCR in the body.” Page 6.

The specification discloses that “[n]ucleotide constructs encoding functional NGPCRs, mutant NGPCRs, as well as antisense and ribozyme molecules can also be used in ‘gene therapy’ approaches for the modulation of NGPCR expression. Thus, the

invention also encompasses pharmaceutical formulations and methods for treating biological disorders.” Page 7.

The NGPCR protein is disclosed to have “a variety of uses, including but not limited to the generation of antibodies, as reagents in diagnostic assays, the identification of other cellular gene products related to a NGPCR, [and] as reagents in assays for screening for compounds that can be used as pharmaceutical reagents useful in the therapeutic treatment of mental, biological, or medical disorders (i.e., heartbeat rate, improper blood pressure, etc.) and disease.” Page 15.

Procedural Background

On August 25, 2004, Appellants were notified of certain similarities between the present case and previously decided Appeal 2003-1794 (commonly assigned application no. 09/804,969). Appellants were ordered (pursuant to 37 CFR § 1.196(d), now 37 CFR § 41.50(d)) to explain why the appeal in this case should not be affirmed on the same basis as previous appeal. On September 24, 2004, Appellants responded to the Rule 196(d) order, pointing out an argument in the Appeal Brief that was not made or addressed in Appeal 2003-1794. See Paper No. 24. “[I]n order to preserve such issues for appeal to the Federal Circuit, . . . Appellants respectfully request[ed] the Board to address all of the assertions of utility set forth by Appellants in the Appeal Brief.” Id., page 3. We therefore proceed to the merits of the appeal.

Discussion

The examiner rejected all of the claims as lacking a disclosed utility sufficient to satisfy 35 U.S.C. § 101.¹ The examiner bears the initial burden of showing that a claimed invention lacks patentable utility. See In re Brana, 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995) (“Only after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince such a person of the invention’s asserted utility.”).

The seminal decision interpreting the utility requirement of § 101 is Brenner v. Manson, 383 U.S. 519, 148 USPQ 689 (1966). At issue in Brenner was a claim to “a chemical process which yields an already known product whose utility—other than as a possible object of scientific inquiry—ha[d] not yet been evidenced.” Id. at 529, 148 USPQ at 693. The Patent Office had rejected the claimed process for lack of utility, on the basis that the product produced by the claimed process had not been shown to be useful. See id. at 521-22, 148 USPQ at 690. On appeal, the Court of Customs and Patent Appeals reversed, on the basis that “where a claimed process produces a known product it is not necessary to show utility for the product.” Id. at 522, 148 USPQ at 691.

The Brenner Court noted that although § 101 requires that an invention be “useful,” that “simple, everyday word can be pregnant with ambiguity when applied to the facts of life.” Id. at 529, 148 USPQ at 693. Thus,

¹ The examiner also rejected all of the claims under 35 U.S.C. § 112, first paragraph, for lack of enablement, but that rejection is merely as a corollary of the finding of lack of utility. See the Examiner’s Answer, page 7. Therefore, our conclusion with respect to the § 101 issue also applies to the § 112 issue.

[it] is not remarkable that differences arise as to how the test of usefulness is to be applied to chemical processes. Even if we knew precisely what Congress meant in 1790 when it devised the “new and useful” phraseology and in subsequent re-enactments of the test, we should have difficulty in applying it in the context of contemporary chemistry, where research is as comprehensive as man’s grasp and where little or nothing is wholly beyond the pale of “utility”—if that word is given its broadest reach.

Id. at 530, 148 USPQ at 694.²

The Court, finding “no specific assistance in the legislative materials underlying § 101,” based its analysis on “the general intent of Congress, the purposes of the patent system, and the implications of a decision one way or the other.” Id. at 532, 148 USPQ at 695. The Court concluded that “[t]he basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point—where specific benefit exists in currently available form—there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.” Id. at 534-35, 148 USPQ at 695.

The Court considered and rejected the applicant’s argument that attenuating the requirement of utility “would encourage inventors of new processes to publicize the event for the benefit of the entire scientific community, thus widening the search for uses and increasing the fund of scientific knowledge.” The Court noted that, while there is value to encouraging disclosure, “a more compelling consideration is that a process patent in the chemical field, which has not been developed and pointed to the degree of

² The invention at issue in Brenner was a process, but the Court expressly noted that its holding “would apply equally to the patenting of the product produced by the process.” Id. at 535, 148 USPQ at 695-96.

specific utility, creates a monopoly of knowledge which should be granted only if clearly commanded by the statute. Until the process claim has been reduced to production of a product shown to be useful, the metes and bounds of that monopoly are not capable of precise delineation. It may engross a vast, unknown, and perhaps unknowable area. Such a patent may confer power to block off whole areas of scientific development.” Id. at 534, 148 USPQ at 695.

The Court took pains to note that it did not “mean to disparage the importance of contributions to the fund of scientific information short of the invention of something ‘useful,’” and that it was not “blind to the prospect that what now seems without ‘use’ may tomorrow command the grateful attention of the public.” Id. at 535-36, 148 USPQ at 696. Those considerations did not sway the Court, however, because “a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.” Id.

Subsequent decisions of the CCPA and the Court of Appeals for the Federal Circuit have added further layers of judicial gloss to the meaning of § 101’s utility requirement. The first opinion of the CCPA applying Brenner was In re Kirk, 376 F.2d 936, 153 USPQ 48 (CCPA 1967). The invention claimed in Kirk was a set of steroid derivatives said to have valuable biological properties and to be of value “in the furtherance of steroidal research and in the application of steroidal materials to veterinary or medical practice.” Id. at 938, 153 USPQ at 50. The claims had been rejected for lack of utility. In response, the applicants submitted an affidavit which purportedly “show[ed] that one skilled in the art would be able to determine the

biological uses of the claimed compounds by routine tests.” Id. at 939, 153 USPQ at 51.

The court held that “nebulous expressions [like] ‘biological activity’ or ‘biological properties’” did not adequately convey how to use the claimed compounds. Id. at 941, 153 USPQ at 52. Nor did the applicants’ affidavit help their case: “the sum and substance of the affidavit appear[ed] to be that one of ordinary skill in the art would know ‘how to use’ the compounds to find out in the first instance whether the compounds are—or are not—in fact useful or possess useful properties, and to ascertain what those properties are.” Id. at 942, 153 USPQ at 53.

The Kirk court held that an earlier CCPA decision, holding that a chemical compound meets the requirements of § 101 if it is useful to chemists doing research on steroids, had effectively been overruled by Brenner. “There can be no doubt that the insubstantial, superficial nature of vague, general disclosures or arguments of ‘useful in research’ or ‘useful as building blocks of value to the researcher’ was recognized, and clearly rejected, by the Supreme Court” in Brenner. See Kirk, 376 F.2d at 945, 153 USPQ at 55.

More recently, in In re Ziegler, 992 F.2d 1197, 26 USPQ2d 1600 (Fed. Cir. 1993), the Federal Circuit considered the degree of specificity required to show utility for a claim to polypropylene. The U.S. application on appeal in Ziegler claimed priority to a German application filed in 1954. “In the German application, Ziegler disclosed only that solid granules of polypropylene could be pressed into a flexible film with a characteristic infrared spectrum and that the polypropylene was ‘plastic-like.’” Id. at 1203, 26 USPQ2d at 1605. “Ziegler did not assert any practical use for the

polypropylene or its film, and Ziegler did not disclose any characteristics of the polypropylene or its film that demonstrated its utility.” Id. The court held that the German application did not satisfy the requirements of § 101 and therefore could not be relied on to overcome a rejection based on an intervening reference. See id., 26 USPQ2d at 1606. “[At] best, Ziegler was on the way to discovering a practical utility for polypropylene at the time of the filing of the German application; but in that application Ziegler had not yet gotten there.” Id., 26 USPQ2d at 1605.

On the other hand, the CCPA reversed a rejection for lack of utility in In re Jolles, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980). The applicant in Jolles claimed pharmaceutical compositions that were disclosed to be useful in treating acute myeloblastic leukemia. See id. at 1323, 206 USPQ at 886. The active ingredients in the compositions were closely related to daunorubicin and doxorubicin, both of which were “well recognized in the art as valuable for use in cancer chemotherapy.” Id., 206 USPQ at 887. The applicant also submitted declaratory evidence showing that eight of the claimed compositions were effective in treating tumors in a mouse model, and one was effective in treating humans. See id. at 1323-24, 206 USPQ at 887-88. The court noted that the data derived from the mouse model were “relevant to the treatment of humans and [were] not to be disregarded,” id. at 1327, 206 USPQ at 890, and held that the evidence was sufficient to support the asserted therapeutic utility. See id. at 1327-28, 206 USPQ at 891.

The Federal Circuit held in Cross v. Iizuka, 753 F.2d 1040, 224 USPQ 739 (Fed. Cir. 1985), that in vivo testing (as in Jolles) was not necessarily required to show utility in the pharmaceutical context. The Cross court stated that “[it] is axiomatic that an

invention cannot be considered ‘useful,’ in the sense that a patent can be granted on it, unless substantial or practical utility for the invention has been discovered and disclosed where such utility would not be obvious.” Id. at 1044, 224 USPQ at 742 (citing Brenner v. Manson). The court “perceive[d] no insurmountable difficulty, under appropriate circumstances, in finding that the first link in the screening chain, in vitro testing, may establish a practical utility for the compound in question.” Id. at 1051, 224 USPQ at 748. Successful in vitro testing could provide an immediate benefit to the public, by “marshal[ling] resources and direct[ing] the expenditure of effort to further in vivo testing of the most potent compounds . . . , analogous to the benefit provided by the showing of an in vivo utility.” Id. On the facts of that case – successful in vitro testing supplemented by similar in vitro and in vivo activities of structurally similar compounds – the court held that in vitro activity was sufficient to meet the requirements of § 101. Id.

The Federal Circuit confirmed in In re Brana, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995), that human testing is not necessary to establish utility for a method of treatment. The invention claimed in Brana was a group of compounds disclosed to have antitumor activity. See id. at 1562, 34 USPQ2d at 1437-38. The claimed compounds were disclosed to have higher antitumor activity than related compounds known to have antitumor activity, and the applicants provided declaratory evidence of in vivo activity against tumors in a mouse model. See id., 34 USPQ2d at 1438. The court held that these data were sufficient to satisfy § 101; usefulness in patent law does not require that the invention be ready to be administered to humans. See id. at 1567, 34 USPQ2d at 1442.

Several lessons can be drawn from Brenner and its progeny. First, § 101's requirement that an invention be "useful" is not to be given its broadest reach, such that little or nothing of a chemical nature would be found to lack utility. See Brenner, 383 U.S. at 530, 148 USPQ at 694. Thus, not every "use" that can be asserted will be sufficient to satisfy § 101. For example, the steroid compound in Brenner was useful as an object of scientific inquiry, and the polypropylene in Ziegler was useful for pressing into a flexible film, yet both lacked sufficient utility to satisfy § 101. See Brenner, 383 U.S. at 529, 148 USPQ at 696; Ziegler, 992 F.2d at 1203, 26 USPQ2d at 1605.

Rather than setting a de minimis standard, § 101 requires a utility that is "substantial", i.e., one that provides a specific benefit in currently available form. Brenner, 383 U.S. at 534-35, 148 USPQ at 695. This standard has been found to be met by pharmaceutical compositions shown to be useful in mouse models and in humans for treating acute myeloblastic leukemia (Jolles, 628 F.2d at 1327-28, 206 USPQ at 891); by evidence showing successful in vitro testing supplemented by similar in vitro and in vivo activities of structurally similar compounds (Cross, 753 F.2d at 1051, 224 USPQ at 748); and by evidence showing in vivo antitumor activity in mice, combined with a disclosure that the claimed compounds had higher antitumor activity than a related compound known to have antitumor activity (Brana, 51 F.3d at 1567, 34 USPQ2d at 1442).

By contrast, Brenner's standard has been interpreted to mean that "vague, general disclosures or arguments of 'useful in research' or 'useful as building blocks of value to the researcher'" would not satisfy § 101. See Kirk, 376 F.2d at 945, 153 USPQ at 55 (interpreting Brenner). Likewise, a disclosure of a "plastic-like" polypropylene

capable of being pressed into a flexible film was held to show that the applicant was “at best . . . on the way to discovering a practical utility for polypropylene at the time of the filing,” but not yet there. Ziegler, 992 F.2d at 1203, 26 USPQ2d at 1605.

In this case, the examiner found the specification’s disclosure to be inadequate:

The instant claims are drawn to a DNA and the protein encoded thereby of as yet undetermined function or biological significance. . . . [I]n the absence of knowledge of the biological significance of this specific polynucleotide and encoded protein, there is no immediately obvious patentable use for the polynucleotide or the encoded protein. . . . [T]he instant specification fails to provide any evidence of record, which would associate the instant DNA or encoded protein with any disease, disorder, or pathological condition, including “heartbeat rate, improper blood pressure”. . . .

Therefore, to employ the instant polynucleotide in the future methods “for use in cell assays and genetically engineered animals” (page 18, lines 12-14) is not a real world [utility] because it would eventually relate to a protein for which no specific biological function is known. . . . Because the instant specification does not teach a specific biological activity of the protein encoded by the claimed polynucleotides, one cannot prevent or treat a condition or disease, such as coronary disease, or “improper blood pressure”, for example, as implied by the specification. To employ the polynucleotide of the instant invention in any of the disclosed methods would clearly be using it as the object of further research, which has been determined by the courts to be a utility, which, alone, does not support patentability.

Examiner’s Answer, pages 4-6.

Appellants argue that “of the pharmaceutical products currently being marketed by the entire pharmaceutical industry, 60% of these drugs target G-protein coupled receptors (Gurrath, 2001, Curr. Med. Chem. 8:1605-1648 . . .). Thus, the biological significance of GPCRs, such as the presently claimed sequences, is clearly well established in the art.” Appeal Brief, page 4.

We do not agree that the characterization of the claimed nucleic acids as encoding G protein-coupled receptors is sufficient to establish their utility. The specification admits that “membrane receptor proteins are often involved in transduction pathways that control cell physiology, chemical communication, and gene expression.” Page 1. The specification provides no information regarding what biological functions or activities involve the polypeptides encoded by the instantly claimed nucleic acids, or what ligands bind to the proteins of SEQ ID NO:2 and SEQ ID NO:4, or what signal is transduced by the proteins in response to ligand binding.

Thus, the record does not support Appellants’ position that the characterization of a polypeptide as a G protein-coupled receptor would have suggested a specific biological function, or any other basis for patentable utility, to a person skilled in the art at the time the application was filed. In the terms used by the Brenner Court, such a characterization does not provide a specific utility in currently available form. We are not persuaded Appellants’ argument that the claimed polynucleotides have utility by virtue of the sequence similarity of the encoded polypeptide to G protein-coupled receptors.

Appellants also argue that the claimed polynucleotides are useful because they encode proteins involved in regulating triglyceride levels. See the Appeal Brief, page 4:

[I]n the response to the Final Action, Appellants noted for the record that the instant application, at least at page 15, lines 25-27, and page 54, line 28, identifies the presently claimed G-protein coupled receptor (GPCR) proteins as involved in medical disorders such as “improper blood pressure” and “coronary disease”. Appellants further noted that this phenotype had been confirmed in mice having genetically engineered mutations in the gene encoding the murine homolog of the presently

described GPCR. Specifically, mice were created in which a portion of the murine homolog of the presently claimed GPCR was deleted, and it was determined that male mice homozygous for this deletion exhibited significantly increased serum triglyceride levels when compared with their wild-type littermates. . . .

See also page 5: “Appellants submit that those of skill in the art, given this data, would readily appreciate the ‘biological significance’ of the presently claimed gene, specifically its role in regulating triglyceride levels.”

Appellants, however, point to nothing in the specification that shows the data asserted in their arguments. Nor do they point to any other evidence of record, such as a research paper or a declaration filed under 37 CFR § 1.132, that provides the data on which their argument is based. We have reviewed the record and have found no evidence showing that the knock-out mice cited in Appellants’ argument were ever made. As far as the record shows, therefore, Appellants’ argument is based on nothing more than hopeful speculation. The record contains no evidence showing that either of the polypeptides encoded by the claimed polynucleotides is involved in triglyceride regulation.³ Appellants’ arguments based on that assertion of utility are therefore unpersuasive.

³ It is true, as Appellants noted, that the examiner in an Interview Summary form referred to “newly obtained data” relating to knock-out mice. See Paper No. 13, mailed January 8, 2003. However, the examiner did not refer to any exhibits or other evidence as constituting those so-called data. Thus, it appears from the record that the examiner was not actually referring to evidence but only to Appellants’ unsupported argument in Paper No. 10. In any case, it is the applicant’s burden to identify the evidence he relies on and explain how that evidence supports his position. See, e.g., *In re Borkowski*, 505 F.2d 713, 718, 184 USPQ 29, 33 (CCPA 1974); *In re Langer*, 503 F.2d 1380, 1395, 183 USPQ 288, 299 (CCPA 1974) (“Appellant’s argument seems to be that one skilled in this art would view similarity in structure as a reliable guide to functional equivalency. . . . Despite the fact that appellant had the burden of rebutting the *prima facie* case, appellant submitted no evidence to support the foregoing argument, and counsel’s argument cannot take the place of evidence.”). Appellants have pointed to no evidence in the record that supports their argument.

Appellants also argue that the claimed nucleic acids are useful in “gene chip” methods of tracking gene expression. See the Appeal Brief, pages 5-6:

Such “DNA chips” clearly have utility, as evidenced by hundreds of issued U.S. Patents. . . . Clearly, compositions that enhance the utility of such DNA chips, such as the presently claimed nucleotide sequences, must in themselves be useful.

Appellants argue that, in addition to their use in “DNA chips”, the claimed sequences are also useful “in mapping the protein encoding regions of the corresponding human chromosome, specifically chromosome 6.” Id., page 7. More particularly, Appellants argue that

[t]he presently claimed polynucleotide sequences provide biologically validated empirical data (e.g., showing which sequences are transcribed, spliced, and polyadenylated) that specifically define that portion of the corresponding genomic locus that actually encodes exon sequence.

Id., page 8. Appellants argue that “the practical scientific value of expressed, spliced, and polyadenylated mRNA sequences is readily apparent to those skilled in the relevant biological and biochemical arts.” Id. Finally, Appellants argue that “the described sequences are useful for functionally defining exon splice-junctions.” Id., page 7.

We are not persuaded by Appellants’ argument. We find that the asserted uses of the claimed polynucleotides—as a component of a DNA chip for monitoring gene expression, as a marker for a given chromosomal locus, or for defining the exon splice-junctions of a gene—do not satisfy the utility requirement of § 101. Such uses do not provide a specific benefit in currently available form.

For example, with regard to the asserted “DNA chip” utility, we accept for argument’s sake that a person skilled in the art could attach one of the claimed polynucleotides (or a part of it) to a solid substrate, in combination with other

polynucleotides, to form a DNA chip, and that such a DNA chip could be used to monitor changes in expression of the corresponding gene. However, the specification provides no guidance to allow a skilled artisan to use data relating to the expression of the gene comprising, e.g., SEQ ID NO:1 in any practical way. The specification provides no guidance regarding what the SEQ ID NO:1-specific information derived from a DNA chip would mean.

For example, assume that a fragment of SEQ ID NO:1 was attached to a DNA chip and the researcher observed that expression of the corresponding gene was increased when a cell was treated with a particular agent. The specification provides no basis on which a skilled worker would be able to determine what, if anything, that result means. Perhaps a change in expression of the gene would mean different things, depending on other factors, but again the specification provides no hint what other factors might be important. Would it depend on what agent is used, what cell type is used, the behavior of other genes (if so, which genes and what behavior is significant), or the degree of increase? Because the specification provides no information about the activity of the protein encoded by SEQ ID NO:1, it provides no guidance as to how to interpret the results of a DNA chip-based gene expression assay based on the claimed polynucleotides.

The same problem afflicts Appellants' assertions that the claimed polynucleotides can be used to map a particular chromosomal locus or to define the exon splice-junctions of the genomic gene: the specification provides no meaningful guidance regarding how to use such information in any practical way. What would it mean, for example, if SEQ ID NO:1 hybridizes to a specific part of human chromosome 6, or if

SEQ ID NO:1 can be used to show that the chromosomal gene has an exon splice junction between nucleotides 103 and 104? The specification provides no guidance on how such information would allow those skilled in the art to use the claimed polynucleotides in a specific, substantial way. By contrast, if the specification disclosed, for example, that SEQ ID NO:1 hybridized adjacent to a chromosomal locus associated with a known disease (e.g., a locus susceptible to a cancer-causing translocation), the sequence would have an apparent utility in disease diagnosis. However, without disclosure of a specific use for the resulting data, using the claimed sequences for mapping or determining exon splice-junctions amounts to research on the claimed polynucleotides themselves.

In effect, Appellants' position is that the claimed polynucleotides are useful because those of skill in the art could experiment with them and figure out for themselves what any observed experimental results might mean. We do not agree that such a disclosure provides a "specific benefit in currently available form." Rather, the instant case seems analogous to Brenner. In Brenner, the applicant claimed a method of making a compound but disclosed no utility for the compound. 383 U.S. at 529, 148 USPQ at 693. The Court held that a process lacks utility if it produces a product that lacks utility. Id. at 534, 148 USPQ at 695. Here, Appellants claim a product asserted to be useful in a method of generating gene-expression or gene-mapping data, but the specification does not disclose how to interpret those data. Just as the process claimed in Brenner lacked utility because the specification did not disclose how to use the end-product, the product claims here lack utility, based on their use in, e.g., DNA chips,

because the specification does not disclose how to use the SEQ ID NO:1-specific gene expression data generated by a DNA chip.

Appellants argue that the claimed polynucleotides could potentially be part of a DNA chip; since DNA chips have utility, compounds that “enhance the utility of such DNA chips, such as the presently claimed nucleotide sequence, must in themselves be useful.” Appeal Brief, pages 5-6. We disagree.

Assuming arguendo that a generic DNA chip—one comprising a collection of uncharacterized or semi-characterized gene fragments—would provide a useful tool for, e.g., drug discovery, it does not follow that each one of the polynucleotides represented in the DNA chip individually has patentable utility. Although each polynucleotide in the DNA chip contributes to the data generated by the DNA chip overall, the contribution of a single polynucleotide—its data point—is only a tiny contribution to the overall picture.

The Brenner Court held that § 101 sets more than a de minimis standard for utility. Therefore, the patentable utility of a DNA chip, for example, does not necessarily mean that every one of the components of the DNA chip also has patentable utility. A patentable utility divided by a thousand does not necessarily equal a thousand patentable utilities. Each claimed invention must be shown to meet § 101’s utility requirement in order to be patentable; it must provide a specific benefit in currently available form. Providing a single data point among thousands, even if the thousands of data points collectively are useful, does not meet this standard.

The Supreme Court noted that the patent system contemplates a basic quid pro quo: in exchange for the legal right to exclude others from his invention for a period of time, an inventor discloses his invention to the public. See Brenner, 383 U.S. at 534,

148 USPQ at 695. The Brenner Court held that the grant of patent rights to an applicant is justified only by disclosure of an invention with substantial utility – a specific benefit in currently available form. Until the invention has been refined and developed to this point, the Court held, the applicant has not met his side of the bargain, and has not provided a disclosure that justifies granting him the right to exclude others. See id.

Thus, the basic quid pro quo of the patent system is the grant of a valuable legal right in exchange for a meaningful disclosure of the claimed invention. In this case, the generic utilities disclosed for the claimed products do not entitle Appellants to the legal right they claim to exclude others from using those products.

We note that this application is one of several on appeal that share the same assignee.⁴ In each of these cases, regardless of the specific facts of the case, the Appellants have asserted the same DNA chip, gene-mapping, and exon splice junction arguments. Apparently, Appellants view these potential uses as utilities that can be asserted for any cDNA they isolate, regardless of how little is known about it, which (they hope) will nonetheless serve as a basis for patent protection and secure for Appellants any value that might become apparent in the future, after they or others have further characterized the claimed products. This is precisely the type of result that the Brenner Court sought to avoid by requiring disclosure of a substantial utility to satisfy § 101. See 148 U.S. at 535-36, 148 USPQ at 696: [The Court was not] “blind to the prospect that what now seems without ‘use’ may tomorrow command the grateful

⁴ Such applications include 09/460,594 (Appeal No. 2003-1528), 09/804,969 (2003-1794); 09/802,116 (2003-2017); 09/822,807 (2003-2028); and 09/564,557 (2004-0343).

attention of the public. But a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.” Id.

The polynucleotides of the instant claims may indeed prove to be useful (and valuable), after the in vivo role of the encoded protein is discovered. The work required to confer value on the claimed products, however, remains to be done. The instant specification’s disclosure does not justify a grant of patent rights. See Brenner, 383 U.S. at 534, 148 USPQ at 695: “[A] process patent in the chemical field, which has not been developed and pointed to the degree of specific utility, creates a monopoly of knowledge which should be granted only if clearly commanded by the statute. Until the process claim has been reduced to production of a product shown to be useful, the metes and bounds of that monopoly are not capable of precise delineation. It may engross a vast, unknown, and perhaps unknowable area. Such a patent may confer power to block off whole areas of scientific development.” We consider the Brenner Court’s concern about the “power to block off whole areas of scientific development” to be equally applicable here.

Finally, adopting the per se rule that Appellants seek—that any expressed human gene has utility because it can be used in a DNA chip—would mean that almost any naturally occurring nucleic acid would be patentable. Appellants’ reasoning does not depend on the biological function of the protein encoded by the claimed nucleic acids, and so would apparently apply to any expressed human gene, as well as fragments of them (see, e.g., the specification at pages 8-9).

Nor can the rationale be confined to expressed human genes. We can take judicial notice of the fact that other organisms are of interest for many different reasons, such that gene expression assays could conceivably be used in their research. For example, some organisms are of interest to researchers because they have been historically well-studied (e.g., yeast and Arabidopsis). Others are of interest because they are used as animal models (e.g., mice and chimpanzees), because they are commercially valuable (e.g., pigs and tomatoes), because they are pests (e.g., ragweed and corn borers), or because they are pathogens (e.g., Candida and various bacteria). Under Appellants' proposed rule, hybridizable fragment of any gene of any of these organisms—and probably most other organisms—would be found to have patentable utility because it could be attached to a chip and used in “research” to see what happens to expression of that gene under various conditions.

Appellants' reasoning would also vitiate the enablement requirement, since “[t]he enablement requirement is met if the description enables any mode of making and using the invention.” Johns Hopkins Univ. v. CellPro Inc., 152 F.3d 1342, 1361, 47 USPQ2d 1705, 1714 (Fed. Cir. 1998) (quoting Engel Indus., Inc. v. Lockformer Co., 946 F.2d 1528, 1533, 20 USPQ2d 1300, 1304 (Fed. Cir. 1991)). If we were to agree with Appellants that any expressed gene and any hybridizable fragment thereof is useful in a DNA chip, then we would also have to hold that the specification has taught those skilled in the art one mode of using the invention. Thus, Appellants' rule of per se utility would also require a corresponding rule of per se enablement.

Under Appellants' rule, then, any polynucleotide from an expressed gene would be patentable if it was adequately described in the specification and was not disclosed or suggested in the prior art. This standard, however, is not the one set by Congress, which requires that a patentable invention also be useful and fully enabled, nor is it the standard that has been consistently applied by the courts.

In addition, the flood of DNA patents that would result from adoption of Appellants' rule could doom the potential contribution of microarrays to biological research. Appellants argue that "[g]iven the widespread utility of such 'gene chip' methods using public domain gene sequence information, there can be little doubt that the use of the presently described novel sequences would have great utility in such DNA chip applications." Appeal Brief, page 15. "[T]here is an entire industry established based on the use of gene sequences or fragments thereof in a gene chip format." Id.

The practical effect of Appellants' utility standard, however, would be that making a microarray with 1000 genes represented on it would require investigating each of the DNA sequences (and subsequences) on the gene chip to ensure that it was not the subject of someone else's patent. For each of the DNAs that was the subject of someone else's patent claim, a license would have to be negotiated – potentially thousands of such negotiations for the finished product. These transaction costs would have to be incurred for each new product that an aspiring gene chip manufacturer wished to market. The industry gridlock likely to result has been termed a "tragedy of the anticommons":

By conferring monopolies in discoveries, patents necessarily increase prices and restrict use—a cost society pays to motivate invention and disclosure. The tragedy of the anticommons refers to the more complex obstacles that arise when a user needs access to multiple patented inputs to create a single useful product. Each upstream patent allows its owner to set up another tollbooth on the road to product development, adding to the cost and slowing the pace of downstream biomedical innovation.

Heller, page 698.⁵

The Supreme Court has warned against allowing too many “tollbooths” on the road to innovation:

Patents . . . are meant to encourage invention by rewarding the inventor with the right, limited to a term of years fixed by the patent, to exclude others from the use of his invention. . . . But in rewarding useful invention, the “rights and welfare of the community must be fairly dealt with and effectually guarded.” Kendall v. Winsor, 21 How. 322, 329 (1859). . . . To begin with, a genuine “invention” or “discovery” must be demonstrated “lest in the constant demand for new appliances the heavy hand of tribute be laid on each slight technological advance in an art.”

Sears, Roebuck & Co. v. Stiffel Co., 376 U.S. 225, 230, 140 USPQ 524, 527 (1964).

Summary

The basic quid pro quo of the patent system requires disclosure of an invention having substantial utility. Appellants’ disclosure in this case does not provide a specific benefit in currently available form, and therefore lacks the substantial utility required by 35 U.S.C. § 101. The rejections for lack of utility are affirmed.

⁵ Heller et al., “Can patents deter innovation? The anticommons in biomedical research,” Science, Vol. 280, pp. 698-701 (1998). Accessible online at www.sciencemag.org/cgi/content/full/280/5364/698.

No time period for taking any subsequent action in connection with this appeal
may be extended under 37 CFR § 1.136(a).

AFFIRMED

William F. Smith)	
Administrative Patent Judge)	
)	
)	
)	BOARD OF PATENT
Demetra J. Mills)	
Administrative Patent Judge)	APPEALS AND
)	
)	INTERFERENCES
)	
Eric Grimes)	
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